EXHIBIT B

CO-DIAGNOSTICS INC.

Co-Diagnostics, Inc. Releases COVID-19 Test Performance Data: Consistently Demonstrates 100% Sensitivity and 100% Specificity Across Independent Evaluations

by Co-Diagnostics | May 1, 2020 | News Release |

Salt Lake City, Utah – May 1, 2020 – Co-Diagnostics, Inc. **(Nasdaq:CODX)** (the Company), a molecular diagnostics company with a unique, patented platform for the development of diagnostic tests, today released COVID-19 test performance data demonstrating 100% sensitivity and 100% specificity, the metrics used to define accuracy in molecular diagnostics testing.

The data being released comes from independent evaluations of the performance of the Company's COVID-19 test in the field. These evaluations were conducted in Mexico by the Mexican Department of Epidemiology ("InDRE"), India, and elsewhere in the US and abroad. Each study concluded 100% concordance for both specificity and sensitivity.

A summary of recent validation data and the data itself can be found here.

In remarking on the test's favorable limit of detection (LOD) results in the evaluations, Brent Satterfield, PhD said, "In diagnostics, the limit of detection or LOD is a single metric that helps inform the key metrics of sensitivity and

specificity but is not relevant as a stand-alone data point. Other metrics that are important are availability, ease of use and throughput. In countries where we have been evaluated against other tests, we have consistently and repeatedly achieved 100% clinical sensitivity and specificity and you can't do better than that."

These results underpin Co-Diagnostics' ongoing role as a major global supplier of COVID-19 tests, providing in-vitro diagnostic kits to nearly 50 countries and domestically to more than a dozen states. On Feb. 24th Co-Diagnostics was the first US-based company to receive a CE marking for a COVID-19 test kit, the regulatory clearance granted by the European Community, followed by Emergency Use Authorization from the US Food & Drug Administration (FDA).

In the United States, Co-Diagnostics has been a supplier for tests around the country including in its home state of Utah, as a supplier for TestUtah, a public-private partnership organized by Silicon Slopes and the State of Utah to "Crush the Curve" in the state. The goals of this initiative include dramatically increasing health assessments, testing capacity and accessibility.

Recently, TestUtah reviewed and commented on testing data reports.

"The level of rigor and expertise at Co-Diagnostics is representative of the amazing Silicon Slopes tech community. We are immensely proud to have them play a key role in the TestUtah initiative and in our mission to expand access to testing across the state," said Clint Betts, executive director, Silicon Slopes.

In addition to its COVID-19 test, the Company has designed, developed and manufactured a wide array of in-vitro diagnostic tests approved by either the European Community or the Central Drugs Standard Control Organization (CDSCO) in India. These tests include tuberculosis, hepatitis B, hepatitis C, malaria, human papillomavirus, Zika, dengue and chikungunya.

The Company's testing technology is also used by leaders in the field of

agriculture and by mosquito abatement districts to detect West Nile virus, eastern equine encephalitis (EEE), western equine encephalitis (WEE), and other mosquito borne pathogens.

About Co-Diagnostics, Inc.:

Co-Diagnostics, Inc., a Utah corporation, is a molecular diagnostics company that develops, manufactures and markets a new, state-of-the-art diagnostics technology. The Company's technology is utilized for tests that are designed using the detection and/or analysis of nucleic acid molecules (DNA or RNA). The Company also uses its proprietary technology to design specific tests to locate genetic markers for use in industries other than infectious disease and license the use of those tests to specific customers.

Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements can be identified by words such as "believes," "expects," "estimates," "intends," "may," "plans," "will" and similar expressions, or the negative of these words. Such forward-looking statements are based on facts and conditions as they exist at the time such statements are made and predictions as to future facts and conditions. Forward-looking statements in this release may include statements regarding the (i) use of funding proceeds, (ii) expansion of product distribution, (iii) acceleration of initiatives in certain verticals or markets, (iv) capital resources and runway needed to advance the Company's products and markets, (v) increased sales in the near-term, (vi) flexibility in managing the Company's balance sheet, (vii) anticipation of business expansion, and (viii) benefits in research and worldwide accessibility of the CoPrimer technology and its cost-saving and scientific advantages. Forward-looking statements are subject to inherent uncertainties, risks and changes in circumstances. Actual results may differ materially from those contemplated or anticipated by such forward-looking statements. Readers of this press release are cautioned not to place undue reliance on any forward-looking

statements. The Company does not undertake any obligation to update any forward-looking statement relating to matters discussed in this press release, except as may be required by applicable securities laws.

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This document contains the following summaries of several studies performed on the Co-Diagnostics Logix Smart™ COVID-19 Test and CoSara Saragene™ Coronavirus (2019) Test along with supportive data:

1. Results from PathWest Laboratories, Australia show 100% agreement with their in-house test, 100% clinical sensitivity and specificity, and 100% accuracy. The clinical results are based on testing 207 samples of nasophryngeal swabs, throat and nose samples, and dry swabs of unknown origin. Additionally, they tested 58 reference samples which showed no cross reactivity of the Logix Smart COVID-19 assay with other respiratory viruses, bacteria, or potential co-infectious pathogens.

2. The Indian National Institute of Pathology ran 45 lower respiratory samples with the Saragene Coronavirus (2019) Test compared with a gold standard Real-Time PCR Test from NIP and the results show 100% sensitivity and specificity. Out of the 45 samples, 10 of the negative samples were from other respiratory viruses. Therefore, the results show no cross reactivity with other viruses.

3. On 22 April, 2020 the Mexican Government's InDRE (CDC equivalent) published the results of their official evaluation and passed Co-Diagnostics' SARS-CoV-2 qPCR virus detection kit (Logix Smart™ COVID-19 kit) for use in Mexico with 13.5 copies/sample statistically reported as the Limit of Detection.

4. We have internal control markers in every test that allow us to monitor 1) the quality of the sample collected 2) the efficiency of the extraction and 3) the sample integrity at the time the test is run. We followed up with Barbara Blanke who is running the program at Timpanogos Regional, and she provided us with data from the internal control for the samples in the latest run. Out of 32 samples, the average Ct was below 25 and was remarkably consistent, revealing that Timpanogos Regional has one of the best sample collection and processing procedures of any group that we have interacted with.

   During our FDA EUA submission, we compared our test side-by-side with the CDC test and found we actually detected more low-level positives than the CDC despite the reported limits of detection.

5. The Minnesota Department of Health comparison data against another assay showing 100% concordance.

VALIDATION REPORT

1. VALIDATION REPORT SCOPE

To report the validation results of the Logix Smart COVID-19 RT-PCR test for sensitivity, specificity, and agreement with a laboratory developed test performed at PathWest Laboratory Medicine WA (Australia).

2. REFERENCED PROCEDURES

Logix Smart COVID-19 Instructions for Use

MIC qPCR System Manual

3. TEST DESCRIPTION

Product Name	Product Number	Validation Site	Analysis Date
Logix Smart COVID-19 RT-PCR Test	COVID-K-001	PathWest Laboratories	30APR2020

4. VALIDATION SUMMARY

All tests were performed using a MIC qPCR System (BioMolecular Systems) with software v2.8.13.

4.1. Cross Reactivity

4.1.1. Protocol: 58 previously characterized reference samples were tested with the Logix Smart COVID-19 Test using a MIC qPCR. The data included three negative controls and three positive controls.

4.1.2. Results: The results were analyzed from MIC Report, Cycling: 2019-nCoV specific RNA with dynamic normalization, fluorescence cut off of 5%, and threshold setting of 1.288 (automatic).

Table 1. Specificity Testing of COVID-K-001

Pathogen	Strain(s)	Logix Result
Negative Sample	unknown	Negative
Negative Sample	unknown	Negative
Adenovirus	1901	Negative
Bocavirus	ex3020735n 10-2	Negative
BDP	1701	Negative
C. pneumonieae	1201 10-3	Negative
C. psitacii	020214 10-2	Negative
Cytomegalovirus	1501 10-2	Negative
Coronavirus	229E 2003 10-2	Negative
Coronavirus	NL63 ex2563866k 10-2	Negative
Coronavirus	OC43 ex-vero TCF 10-2	Negative
Epstein-Barr Virus	1701	48.06 cycles
Enterovirus	1501 10-1	Negative
ER71	1501	Negative

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ER71B	1501 10-2	Negative
Influenza A Matrix	1401 10-3	Negative
Influenza B	1901	Negative
Influenza C	1301 10-2	Negative
Streptococcus Group A	1701	Negative
Streptococcus Group B	1701	Negative
H. influenzae	1201 10-3	Negative
H1N1	2009 1401 10-3	Negative
H3N2	1501 10-1	Negative
H5N1	1401 10-2	Negative
H7N9	1401 10-5	Negative
HHV-6a	1801	Negative
HHV-6b	1601	Negative
HHV-8	1601	Negative
Herpes Simplex Virus, type 1	1401 10-3	Negative
Herpes Simplex Virus, type 2	1701 10-1	Negative
K. pneaumoniae	1801	Negative
L. longbeachae	1301 10-3	Negative
L. pneumophila	1501 10-4	Negative
M. pneumoniae	1501 10-3	Negative
M. tuberculosis	1301 10-1	Negative
Measles	1201 10-2	Negative
MSD	1901	Negative
Mumps	1201 10-2	Negative
N. gonorrhea	1401 10-3	Negative
Negative Control (Kit)		Negative
Negative Control (Kit)		Negative
Negative Control (Kit)		Negative
NMDA	WACC787 10-1	46.86
NMDB	1601 10-2	Negative
NMDC	1301 10-3	Negative
NMDW	1601 10-3	Negative
NMDX	WACC788 10-3	Negative
NMDY	1801	Negative
NMDZ	WACC789 10-2	Negative
P.aeruginosa	ATCC27853 10-2	Negative
Parecho	1401 10-3	Negative
PF1/HMR	1801/1701	Negative
PF2/3	1901	Negative
Positive Control (Kit)		26.50
Positive Control (Kit)		25.77
Positive Control (Kit)		25.78
Rhinovirus	1503 10-1	Negative
RSV A/B	1801	Negative
Rubella	1801 10-1	Negative
SARS CoV RNA	10-2	34.69
SARS-CoV	1001 10-2	Negative
Staphylococcus aureus	1401 10-2	Negative
Streptococcus pneumoniae	1201 10-3	Negative

Varicella zoster virus	1201 10-4	Negative

4.1.3. Conclusions: According to the instructions for use for the Logix assay, any amplification past cycle 45 is outside the range of the assay. Therefore, the results for specificity show only positive reactions for SARS CoV RNA and the positive control. The information sent to CoDx does not identify which strain of SARS CoV is showing positive. No other cross reactivity was identified.

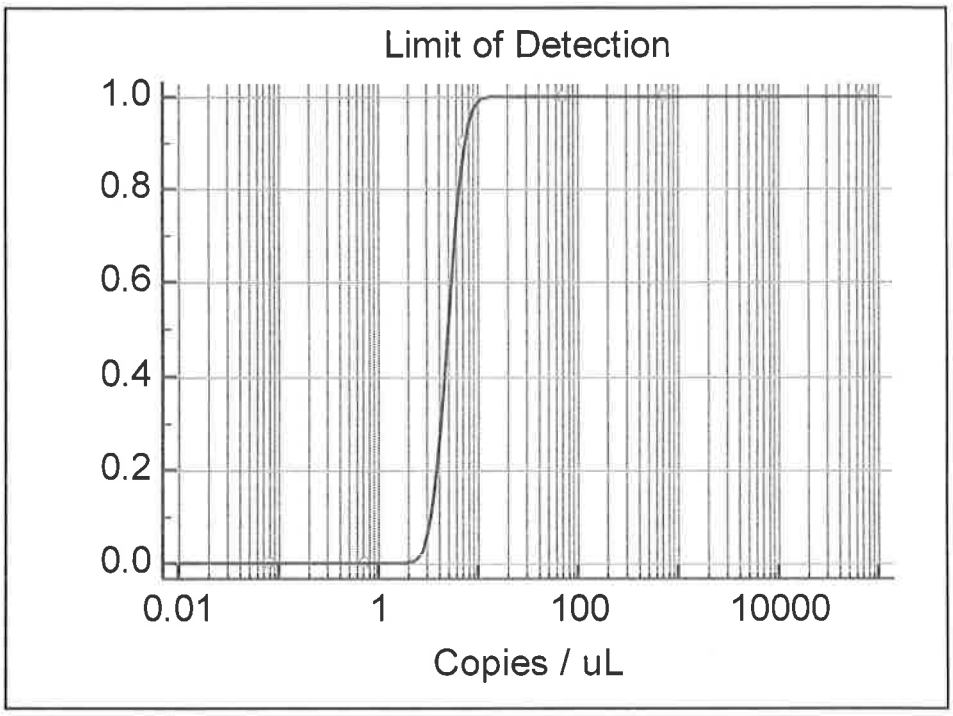
4.2. Sensitivity

4.2.1. Protocol: The limit of detection was determined by taking a known concentration of COVID-19 RNA and serial diluting it on a 9 point scale. Each concentration was ran in replicates of 7-10.

4.2.2. Results: The results were reported in Excel worksheet "Codiagnostics Logix Smart COVID-19 LoD".

Table 2. Sensitivity Results for 9-point Scale

Titre	Copy Number - 2SD	Copy Mean	Copy + 2SD	Ct Mean	Ct σ	Total	Detected
Neat	63093187.93	75166666.67	87240145.41	No Test	No Test	No Test	No Test
1.00E-01	6309318.79	7516666.67	8724014.54	No Test	No Test	No Test	No Test
1.00E-02	630931.88	751666.67	872401.45	No Test	No Test	No Test	No Test
1.00E-03	63093.19	75166.67	87240.15	23.08	1.05	8	8
1.00E-04	6309.32	7516.67	8724.01	25.96	0.63	10	10
1.00E-05	630.93	751.67	872.40	29.13	0.51	10	10
1.00E-06	63.09	75.17	87.24	32.88	0.56	20	20
1.00E-07	6.31	7.52	8.72	35.66	0.97	10	9
1.00E-08	0.63	0.75	0.87	0.00	0.00	7	0
1.00E-09	0.06	0.08	0.09	0.00	0.00	7	0



The probability from 0.01 to 0.99 was calculated for copies/uL. The 95% limit of detection was calculated at 8.42 copies/uL (42.1 copies per reaction).

Table 3. Limit of Detection Probability

Probability	Copies / uL
0.01	2.45
0.02	2.66
0.03	2.74
0.05	3.03
0.10	3.39
0.20	3.88
0.25	4.09
0.50	5.05
0.75	6.23
0.80	6.56
0.90	7.52
0.95	**8.42**
0.98	9.29
0.98	9.56
0.99	10.41

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4.2.3. Conclusions: The calculated limit of detection based on the titre was 8.42 copies/uL.

4.3. Agreement with LDT or clinical sensitivity/specificity

4.3.1. Protocol: 207 patient samples from nasopharyngeal swab, nose and throat, and dry swab of unspecified site were testing using the Logix Smart COVID-19 Kit and a laboratory developed RT-PCR assay.

4.3.2. Results: The results were analyzed in Excel worksheet "Kurabo and Codiagnostics Logix Smart COVID-19 Patient Validation".

Table 4. Patient Results for Logix vs. LDT

Sample Name	Decision - Logix Smart	Decision - In House LDT	Sample Type
1070758N	COVID-19 Positive	COVID-19 Positive	Nose and Throat
1105831X	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2551011Y	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2551344J	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2551659Y	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2551671F	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2551682E	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2551686F	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2551756R	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2551998A	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2552019U	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2552298D	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2552821P	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
2552921C	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2552924X	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2554001P	Negative COVID-19	Negative COVID-19	Nose and Throat
2554002W	Negative COVID-19	Negative COVID-19	Nose and Throat
2554003C	Negative COVID-19	Negative COVID-19	Nose and Throat
2554005Q	Negative COVID-19	Negative COVID-19	Nose and Throat
2554006X	Negative COVID-19	Negative COVID-19	Nose and Throat
2560030S	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
2560103Y	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2560700G	Negative COVID-19	Negative COVID-19	Nose and Throat
2560704H	Negative COVID-19	Negative COVID-19	Nose and Throat
2562999M	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2563202N	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568019Y	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568071A	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
2568117Y	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
2568169Ya	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568169Yb	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568194S	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
2568202L	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
2568232N	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
2568238C	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
2568239J	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
2568255S	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
2568356M	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568361Xa	COVID-19 Positive	COVID-19 Positive	Nose and Throat

2568361Xb	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568380Aa	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568380Ab	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568382N	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568471C	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568479E	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568482B	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568535X	Negative COVID-19	Negative COVID-19	Nose and Throat
2568536D	Negative COVID-19	Negative COVID-19	Nose and Throat
2568537K	Negative COVID-19	Negative COVID-19	Nose and Throat
2568538R	Negative COVID-19	Negative COVID-19	Nose and Throat
2568539Y	Negative COVID-19	Negative COVID-19	Nose and Throat
2568540G	Negative COVID-19	Negative COVID-19	Nose and Throat
2568541N	Negative COVID-19	Negative COVID-19	Nose and Throat
2568542U	Negative COVID-19	Negative COVID-19	Nose and Throat
2568543B	Negative COVID-19	Negative COVID-19	Nose and Throat
2568544H	Negative COVID-19	Negative COVID-19	Nose and Throat
2568545P	Negative COVID-19	Negative COVID-19	Nose and Throat
2568546W	Negative COVID-19	Negative COVID-19	Nose and Throat
2568547C	Negative COVID-19	Negative COVID-19	Nose and Throat
2568548J	Negative COVID-19	Negative COVID-19	Nose and Throat
2568550Z	Negative COVID-19	Negative COVID-19	Nose and Throat
2568551F	Negative COVID-19	Negative COVID-19	Nose and Throat
2568619B	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568652A	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568691N	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568705W	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568706C	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568715N	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568757W	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
2568778M	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
2568783X	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
2568829U	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2568831K	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569436K	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569486X	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569488K	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569489R	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569491G	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569495H	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569498C	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569500G	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569504H	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569505P	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569507C	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569508J	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569512M	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569516N	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569521Y	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569541H	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569604W	Negative COVID-19	Negative COVID-19	Nasopharyngeal Swab

2569610M	Negative COVID-19	Negative COVID-19	Nose and Throat
2569613G	Negative COVID-19	Negative COVID-19	Nose and Throat
2569618P	Negative COVID-19	Negative COVID-19	Nose and Throat
2569619W	Negative COVID-19	Negative COVID-19	Nose and Throat
2569624F	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569625M	Negative COVID-19	Negative COVID-19	Nose and Throat
2569628G	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569629N	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569650G	Negative COVID-19	Negative COVID-19	Nasopharyngeal Swab
2569655P	Negative COVID-19	Negative COVID-19	Nasopharyngeal Swab
2569656W	Negative COVID-19	Negative COVID-19	Nasopharyngeal Swab
2569657C	Negative COVID-19	Negative COVID-19	Nasopharyngeal Swab
2569658J	Negative COVID-19	Negative COVID-19	Nasopharyngeal Swab
2569659Q	Negative COVID-19	Negative COVID-19	Nasopharyngeal Swab
2569660Z	Negative COVID-19	Negative COVID-19	Nasopharyngeal Swab
2569696Q	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569697X	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569702W	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569934M	Negative COVID-19	Negative COVID-19	Nose and Throat
2569935T	Negative COVID-19	Negative COVID-19	Nose and Throat
2569936A	Negative COVID-19	Negative COVID-19	Nose and Throat
2569937G	Negative COVID-19	Negative COVID-19	Nose and Throat
2569938N	Negative COVID-19	Negative COVID-19	Nose and Throat
2569939U	Negative COVID-19	Negative COVID-19	Nose and Throat
2569940D	Negative COVID-19	Negative COVID-19	Nose and Throat
2569941K	Negative COVID-19	Negative COVID-19	Nose and Throat
2569942R	Negative COVID-19	Negative COVID-19	Nose and Throat
2569943Y	Negative COVID-19	Negative COVID-19	Nose and Throat
2569953Q	Negative COVID-19	Negative COVID-19	Nose and Throat
2569954X	Negative COVID-19	Negative COVID-19	Nose and Throat
2569955D	Negative COVID-19	Negative COVID-19	Nose and Throat
2569956K	Negative COVID-19	Negative COVID-19	Nose and Throat
2569958Y	Negative COVID-19	Negative COVID-19	Nose and Throat
2569959E	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2569960N	Negative COVID-19	Negative COVID-19	Nose and Throat
2569961U	Negative COVID-19	Negative COVID-19	Nose and Throat
2569988A	Negative COVID-19	Negative COVID-19	Nose and Throat
2569989G	Negative COVID-19	Negative COVID-19	Nose and Throat
2569990Q	Negative COVID-19	Negative COVID-19	Nose and Throat
2569991X	Negative COVID-19	Negative COVID-19	Nose and Throat
2569992D	Negative COVID-19	Negative COVID-19	Nose and Throat
2569993K	Negative COVID-19	Negative COVID-19	Nose and Throat
2569994R	Negative COVID-19	Negative COVID-19	Nose and Throat
2569996E	Negative COVID-19	Negative COVID-19	Nose and Throat
2569998S	Negative COVID-19	Negative COVID-19	Nose and Throat
2569999Z	Negative COVID-19	Negative COVID-19	Nose and Throat
2570000B	Negative COVID-19	Negative COVID-19	Nose and Throat
2571038A	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2571304Lb	Negative COVID-19	Negative COVID-19	Nose and Throat
2571304La	Negative COVID-19	Negative COVID-19	Nose and Throat
2572177W	COVID-19 Positive	COVID-19 Positive	Nose and Throat

2572718B	COVID-19 Positive	COVID-19 Positive	Nose and Throat
2572913Ua	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
2572913Ub	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
2572923M	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
2572941J	COVID-19 Positive	COVID-19 Positive	Nose and Throat
3086145U	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
3238784E	COVID-19 Positive	COVID-19 Positive	Nose and Throat
3238901X	COVID-19 Positive	COVID-19 Positive	Dry swab, site unspecified
3239267T	COVID-19 Positive	COVID-19 Positive	Nose and Throat
3239268A	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
3239299J	Negative COVID-19	Negative COVID-19	Nose and Throat
3239766C	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
3323086X	Negative COVID-19	Negative COVID-19	Nose and Throat
3482823C	COVID-19 Positive	COVID-19 Positive	Nose and Throat
3564711F	Negative COVID-19	Negative COVID-19	Nose and Throat
3660657C	COVID-19 Positive	COVID-19 Positive	Dry swab, site unspecified
3660722F	COVID-19 Positive	COVID-19 Positive	Nose and Throat
3661013Y	Negative COVID-19	Negative COVID-19	Nasopharyngeal Swab
3709292C	Negative COVID-19	Negative COVID-19	Nose and Throat
3709293J	Negative COVID-19	Negative COVID-19	Nasopharyngeal Swab
3709347L	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
3709348S	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
3733499P	Negative COVID-19	Negative COVID-19	Nasopharyngeal Swab
3754925Y	Negative COVID-19	Negative COVID-19	Nose and Throat
3754942N	Negative COVID-19	Negative COVID-19	Nose and Throat
3754943U	Negative COVID-19	Negative COVID-19	Nose and Throat
3754944B	Negative COVID-19	Negative COVID-19	Nose and Throat
3777430Y	Negative COVID-19	Negative COVID-19	Nose and Throat
3777435F	Negative COVID-19	Negative COVID-19	Throat
3777448S	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
3814560T	COVID-19 Positive	COVID-19 Positive	Dry swab, site unspecified
3815985H	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
3816064T	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
3816066G	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
3816068U	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
3816070K	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
3816080C	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
3816082Q	Negative COVID-19	Negative COVID-19	Dry swab, site unspeci-

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			fied
3816094W	Negative COVID-19	Negative COVID-19	Nose and Throat
3816101H	Negative COVID-19	Negative COVID-19	Nose and Throat
3816103W	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
3816107X	Negative COVID-19	Negative COVID-19	Nose and Throat
3816109K	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
3885284L	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
3886426Q	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
3886504F	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
3998210M	Negative COVID-19	Negative COVID-19	Nose and Throat
4022921R	Negative COVID-19	Negative COVID-19	Nose and Throat
4067378M	COVID-19 Positive	COVID-19 Positive	Nose and Throat
4067382Q	COVID-19 Positive	COVID-19 Positive	Nose and Throat
4067833A	Negative COVID-19	Negative COVID-19	Nose and Throat
4094647R	COVID-19 Positive	COVID-19 Positive	Nose and Throat
4094967Q	Negative COVID-19	Negative COVID-19	Dry swab, site unspecified
9083211B	COVID-19 Positive	COVID-19 Positive	Nose and Throat
9095096X	COVID-19 Positive	COVID-19 Positive	Nose and Throat
9097010H	COVID-19 Positive	COVID-19 Positive	Nose and Throat
9097326D	COVID-19 Positive	COVID-19 Positive	Nose and Throat
9097773Y	COVID-19 Positive	COVID-19 Positive	Nose and Throat
9098380N	COVID-19 Positive	COVID-19 Positive	Nose and Throat
9099242N	COVID-19 Positive	COVID-19 Positive	Nasopharyngeal Swab
9100422K	COVID-19 Positive	COVID-19 Positive	Nose and Throat
9101647Y	COVID-19 Positive	COVID-19 Positive	Nose and Throat
9101873A	COVID-19 Positive	COVID-19 Positive	Dry swab, site unspecified
9102097B	COVID-19 Positive	COVID-19 Positive	Dry swab, site unspecified
9105135F	COVID-19 Positive	COVID-19 Positive	Dry swab, site unspecified
9114883M	Negative COVID-19	Negative COVID-19	Nasopharyngeal Swab

Table 5. Sample Types

Sample Type	Count
Nose and Throat	152
Nasopharyngeal	30
Site Unspecified	24
Throat	1

Table 6. Patient Sample Results Summary			
	Laboratory Developed RT-PCR Test		
	Positive	Negative	Total
Logix Positive	103	0	
Logix Negative	0	104	
Total			207

4.3.3. Conclusions: The testing of patient samples showed 100% agreement with 100% sensitivity (CI 96.48-100) and specificity (CI 96.52-100) between the LDT RT-PCR test and the Logix Smart COVID-19 Test. Accuracy was determined to be 100% (CI 98.23-100).

5. ATTACHMENTS

Attachment A: Kurabo and Codiagnostics Logix Smart COVID-19 Patient Validation
Attachment B: Co-diagnostics Logix Smart COVID-19 LoD
Attachment C: Co-diagnostics Logix Smart COVID-19 Cross Reactivity Testing
Attachment D: MIC Run Files

	Signature	Date
Author	Ruben Gomez	**30APR2020**
Supervisor	Ruben Gomez	30APR2020

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ATTACHMENT 2

CO-DIAGNOSTICS INC.

Report
Validation Report

VALIDATION REPORT

1. VALIDATION REPORT SCOPE

To report the validation results of the Logix Smart™ COVID-19 RT-PCR Test which was manufactured by Cosara Diagnostics Pvt. Ltd. and re-branded Saragene™ Corona Virus (2019 NCV) RT-PCR Test. This report shares the sensitivity, specificity, and agreement of the Logix Test with a laboratory developed test performed at the National Institute of Pathology, India.

2. REFERENCED PROCEDURES

Logix Smart COVID-19 Instructions for Use

Quant Studio Flex 7 Manual

3. TEST DESCRIPTION

Product Name	Product Number	Validation Site	Analysis Date
Saragene Corona Virus 2019 RT-PCR Test	20C11PE-01	National Institute of Pathology, India	24APR2020

4. VALIDATION SUMMARY

All tests were performed using a QuantStudio 7 (ThermoFisher).

4.1. Agreement with LDT or clinical sensitivity/specificity

4.1.1. Protocol: 45 samples from upper respiratory, lower respiratory, and serum were testing using the Saragene Kit and compared against the ICMR-NIV gold standard RT-PCR assay. Of the 45 samples, 18 were positive at low, medium and high levels and 18 were negative. They also included samples that were negative for COVID-19 but positive for influenza A, influenza B, or other respiratory viruses.

4.1.2. Results: The results were analyzed reported in letterhead "Covid-19/NIP/Evaluation/123" to CDSCO and Cosara Diagnostics Pvt. Ltd.

Table 1. Patient Sample Results Summary

	NIV Gold Standard RT-PCR Test		
	Positive	Negative	Total
Logix Positive	18	0	18
Logix Negative	0	27	27
Total	18	27	45

4.1.3. Conclusions: The testing of patient samples showed 100% agreement with 100% sensitivity (CI 85.4-100) and specificity (CI 78.1-100) between the

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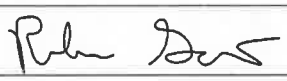
NIV RT-PCR test and the Saragene Corona Virus (2019 NCV) Test. Accuracy was determined to be 100% with no cross reactivity to other respiratory viruses.

5. ATTACHMENTS

Attachment A: ICMR- National Institute of Pathology Letterhead with Results

	Signature	Date
Author		**30APR2020**
Supervisor		**30APR2020**

CO-DIAGNOSTICS

Memo: InDRE Evaluation Co-Diagnostics' COVID-19 IVD qPCR detection kit
30 April, 2020

On 22 April, 2020 the Mexican Government's InDRE (CDC equivalent) published the results of their official evaluation and passed Co-Diagnostics' SARS-CoV-2 qPCR virus detection kit (Logic Smart™ COVID-19 kit.) for use in Mexico. The validation was performed on an ABI 7500 FAST instrument, using the same protocol specified in the Co-Dx Instructions for Use.

Minimum criteria, as seen in the document contained in the internet link below

1) 250 copies / reaction detection limit of detection
2) 100% analytic specificity, referring to no empirical cross-reactivity with other respiratory viruses tested
3) Reproducibility should be greater or equal than 95% in accordance with referenced standards.

Reference (in Spanish)
https://www.gob.mx/cms/uploads/attachment/file/547178/Criterios_para_la_aceptaci_n_de_pruebas_moleculares_para_el_diagn_stico_de_SARS-CoV-2.pdf

A document was produced and readily available on the web showing the analytical testing to verify performance claims by the manufacturer. This document can be seen here
https://www.gob.mx/cms/uploads/attachment/file/547725/Kit_para_Coronavirus_2019_Logix_SmarthTM_COVID-19_Raver_Aplicaciones_.pdf

Below is a summary of the findings of the above link.

Clinical Specificity (Cross-Reactivity with other Viruses)

Samples containing various verified respiratory viruses (but negative for SARS-CoV-2) were run using Logic Smart COVID-19 kit.

These samples were: Three Human Metapneumovirus samples, one Parainfluenza type 4, one Parainfluenza type 3, and three typical coronavirus (consisting of one NL63 and two HKU1) samples.

All were negative using CoDiagnostics' test, as expected.

Limit of detection (LOD)

LOD was assessed by using extracted and quantified total RNA obtained from a SARS-CoV-2 positive clinical sample.

Different concentrations of this extract were used, with 5 replicates per concentration. This analysis was done with the same operator using the same CoDiagnostics lot 200320-k-205, with the result of 100% detection of 10 copies / reaction. Statistically, the result of 13.5 copies was reported as LOD, detected in 5 uL of sample delivered to the final qPCR reaction.

Repeatability

Various concentrations of the clinical extracted RNA were analyzed in replicates of 5 and 5/5 reactions were positive for 1,000, 250, 100, and 10 copies / reaction.

A final statement was made that the manufacturer's LOD value, and specificity were concordant with empirical results obtained by the InDRE testing and that during the emergency period (time frame not specified) this reagent is valid for use in Mexico (as FDA EUA).

ATTACHMENT 4

CO-DIAGNOSTICS INC.

MULTIPLE MARKERS AND COVID-19

Why Multiple Markers?

PCR tests have been plagued with false amplification products called primer-dimers from the invention of PCR in the 1980's. These primer-dimers can contribute to false positives and are made even worse in single-step reverse-transcriptase PCR tests for RNA genomes such as COVID-19. Not even commercial hot starts are sufficient to suppress false positives from these spurious amplification products.

Methods to increase specificity include using additional markers to rule out false positives from primer-dimers. Unfortunately, adding more primers to the same well compounds the primer-dimer issue. Therefore, despite the higher reagent cost, lower throughput, and worse limit of detection, test developers will often put the primers for each marker in separate wells.

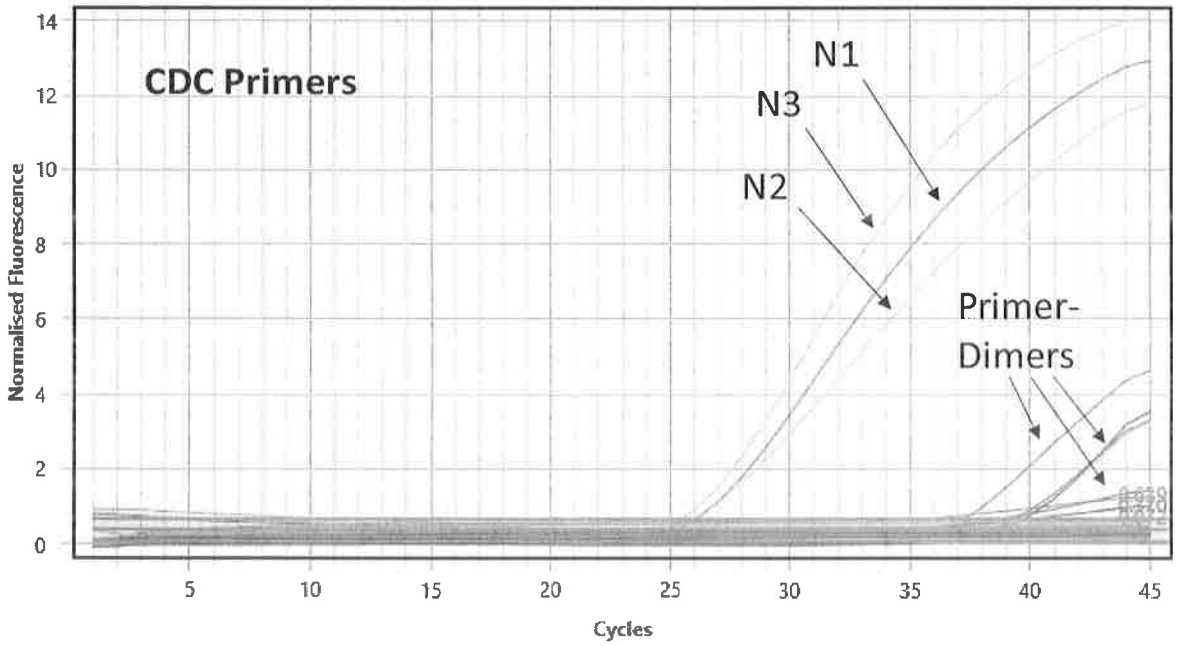


Figure 1. Primer-Dimers in CDC test. Primer-dimers require multiple markers to eliminate false positives. They require each marker to be run in a separate well, increasing labor and reagent cost while reducing throughput and sensitivity.

Is There a Better Solution?

Co-Diagnostics developed CoPrimers, an advanced primer technology that couples a very short primer with a probe. This cooperative interaction reduces primer-dimer formation by up to 2.5 million times relative to the primers used in other tests. In other words, *it increases specificity without having to use multiple markers.*

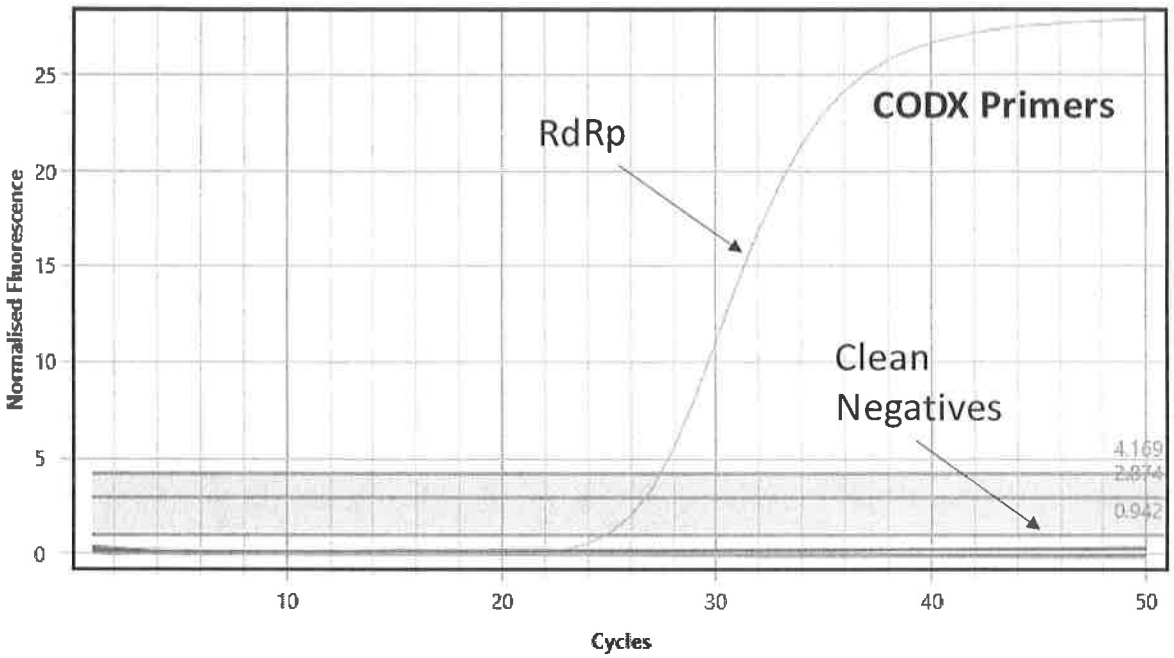


Figure 2. CoPrimers in the Co-Diagnostics Test Eliminate Primer-Dimers. In hundreds of runs with negative controls in various sample matrices for COVID-19, no primer-dimer positives have been observed.

Does Testing with a Single Marker Work?

In a randomized study with ninety sputum samples spiked with COVID-19 viral genomes[1] and ninety negative samples, the Co-Diagnostics test outperformed the CDC primer set detecting a greater number of low-level positives. The Co-Diagnostics primer set had 100% sensitivity and 100% specificity in this study. Because the CDC primer set requires viral genomes to be present in each well for each of the three markers to be positive, it is three times less likely to detect low-level positives.

The Co-Diagnostics test detects more low-level positives than the CDC primer set.

Not only did the Co-Diagnostics test outperform the CDC primer set, but the use of a single marker in a single well provides several additional benefits: 1) The Co-Diagnostics test can run four times as many samples as the CDC test in the same time and on the same machine. 2) It requires less reruns from "indeterminate" results (eg results where one or two of the three markers is present, but not all three). 3) It uses less reagents. 4) It is easier to analyze, allowing automated analysis by most real-time PCR machines.

[1] Sputum samples were spiked with four different concentrations of the COVID-19 genome. The genomic material was deposited by the Centers for Disease Control and Prevention and obtained through BEI Resources, NIAID, NIH: Genomic RNA from SARS-Related Coronavirus 2, Isolate USA-WA1/2020, NR-52285.

CoPrimers Increase Test Stability

With multiple markers taking up multiple wells, it can take several hours to run a decent number of samples. We observed that the Co-Diagnostics test is more stable over time than the CDC primer set when left at 4C in a refrigerator.

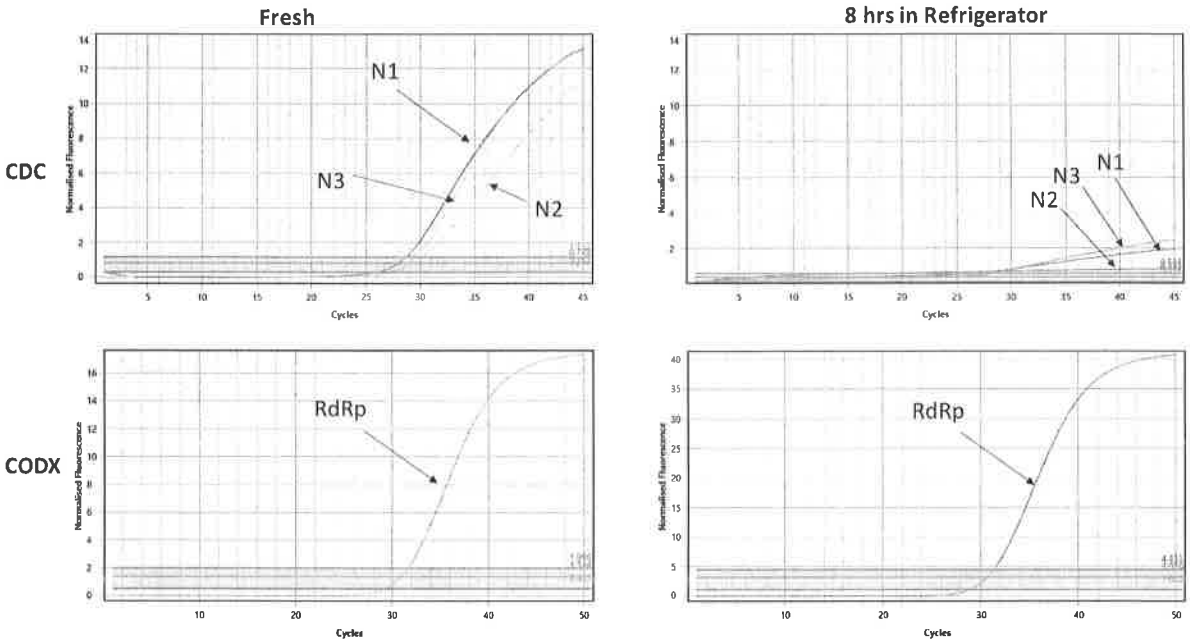


Figure 3. Stability of CDC primers vs CODX primers. The three markers in the CDC primer set experienced significant deterioration in signal after eight hours in a refrigerator, resulting in an increase in false negative results. The Co-Diagnostics test had no loss in signal even after eight hours.

Conclusion

Co-Diagnostics is able to do what other labs cannot because it has the most advanced primer technology on the market. CoPrimers reduce primer-dimers by 2.5 million times relative to standard PCR primers and probes. This allows for a more stable single-marker, single-well test that is lower cost, higher throughput, and easier to use/analyze.

Sample	Date Received	AGCL Accession	DOH Accession	Result in Ct			Concordant
				MN DOH	COV-FAM	IC CalFluor-RED	
1	4/10/20	202004-15022	2020310691	25.51	26.15	26.26	1
2	4/10/20	202004-15024	2020310776	19.05	18.52	26.67	1
3	4/10/20	202004-15026	2020310947	31.73	31.95	25.85	1
4	4/10/20	202004-15028	2020310957	19.35	18.32	26.55	1
5	4/10/20	202004-15030	2020311459	28.18	27.16	24.29	1
6	4/10/20	202004-15032	2020311616	16.82	18.12	24.28	1
7	4/10/20	202004-15034	2020311887	20	17.24	21.72	1
8	4/10/20	202004-15036	2020312109	24.83	24.99	28.22	1
9	4/10/20	202004-15038	2020312420	31.75	32.14	28.47	1
10	4/10/20	202004-15020	2020312424	20.05	20.3	27.05	1
11	4/10/20	202004-15004	2020312274	Negative		23.66	1
12	4/10/20	202004-15006	2020312298	Negative		27.81	1
13	4/10/20	202004-15008	2020312299	Negative		25.78	1
14	4/10/20	202004-15010	2020312301	Negative		25.3	1
15	4/10/20	202004-15012	2020312304	Negative		23.45	1
16	4/10/20	202004-15013	2020312309	Negative		24	1
17	4/10/20	202004-15014	2020312310	Negative		26.37	1
18	4/10/20	202004-15016	2020312318	Negative		24.65	1
19	4/10/20	202004-15018	2020312319	Negative		25.39	1
20	4/10/20	202004-15002	2020312320	Negative		29.48	1
							100%